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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,643	12/12/2001	Michael O. Thorner	033493-001	9752

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EXAMINER	
KAUFMAN, CLAIRE M	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 05/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/009,643	THORNER ET AL.	
	Examiner	Art Unit	
	Claire M. Kaufman	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 March 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *5-7 and 15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5-7 and 15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

RD

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group II in the reply filed on 2/2/05 is acknowledged.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

Claims 5, 6, 7 and 15 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Since the claimed DNA and protein is naturally occurring in chicken pituitary or hypothalamic cells and is not claimed as purified and/or isolated, the claims do not show the hand of man involved in the invention and, therefore, are unpatentable. See MPEP § 706.03(a) and 2105.

Specification

The disclosure is objected to because of the following informalities: on page 2, line 28, "responding" should be –responds-- ; p. 7, line 4, "B" should be "1"; p.13, lines 27-28, 14, line 11, and p. 15, lines 24, there is no number for "SEQ ID NO:".

Appropriate correction is required.

The specification is replete with grammatical and idiomatic errors too numerous to mention specifically. The specification should be revised carefully. Examples of such errors are give above.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 7 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a chicken GHRH receptor having the amino acid sequence of SEQ ID NO:4, does not reasonably provide enablement for other chicken GHRH receptors. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

There are several issues associated with enablement of this claim. The first, which leads into the others, is the question of what is required of a protein to be a "chicken GHRH receptor". The instant specification discusses both origin of cloning as well as activity. As to origin, there is no GHRH receptor which has been isolated from chicken which contains substitution of conservative amino acids within SEQ ID NO:5 in the specification or prior art. Therefore, it would reasonably appear that a "chicken GHRH receptor" does not need to have the same sequence as a receptor found in a chicken. As to activity, SEQ ID NO:5 is described only as an immunogenic fragment with no ligand binding or signal transduction activity (p. 10, line 20). There is no functional limitation in this claim. The claim is similar to a single means claim (MPEP § 2164.08(a)), *i.e.*, where a means recitation does not appear in combination with another recited element of means, is subject to an undue breadth rejection under 35 U.S.C. 112, first paragraph. *In re Hyatt*, 708 F.2d 712, 218 USPQ 195 (Fed. Cir. 1983) A single means claim which covered every conceivable means for achieving the stated purpose was held nonenabling for the scope of the claim because the specification disclosed at most only those means known to the inventor. In the instant case, the claim recites a fragment that is 5% of the length of the full-length disclosed protein of which it is a part or a variant of the fragment, and a term--chicken GHRH receptor--which is apparently intended to limit the claim's scope, though it is not clear how.

The specification discloses a single chicken GHRH receptor: SEQ ID NO:4. The prior art identified a putative GHRH receptor in chicken pituitary based on binding of human GHRH. On page 2 of the specification, lines 1-5, it taught that, "Furthermore, Southern blot analysis, using a human GHRH receptor probe and genomic DNA from human, monkey, rat, mouse, dog, cow, rabbit, chicken and yeast, detected GHRH receptors in all mammals tested, but not in chicken or yeast. These results indicate that GHRH receptors are well conserved in all the

mammals tested, but absent or less well conserved in the chicken." The specification does not provide guidance or examples of what function(s) or structure, aside from SEQ ID NO:4, is necessary for a protein to be considered a "chicken GHRH receptor". The prior art also fails to provide information in the form of guidance or examples to allow the skilled artisan to make a "chicken GHRH receptor" without undue experimentation. For these reasons which include the structural breadth of the claim and lack of functional limitation, the complexity of the art related to existence and function of a chicken GHRH receptor, and the lack of guidance and examples about the existence and/or making of a chicken GHRH receptor other than SEQ ID NO:4, it would require undue experimentation to practice the invention commensurate in scope with the claim.

Claim Rejections - 35 USC § 112

Claim 7 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification discloses SEQ ID NO:4, the sequence of a chicken GHRH receptor identified by Applicant. SEQ ID NO:4 meets the written description provision of 35 USC 112, first paragraph. However, the claims are directed to or encompass sequences that contain SEQ ID NO:5 with or without 1-3 conservative amino acid substitution but which must be a "chicken GHRH receptor", which at least includes mutated sequences, allelic variants and splice variants of SEQ ID NO:4. None of these sequences meets the written description provision of 35 USC 112, first paragraph.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116).

With the exception of SEQ ID NO:4, the skilled artisan cannot envision the detailed chemical structure of the encompassed proteins, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The protein itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence. In this instance, only a single chicken GHRH receptor has been described, not a broad class of proteins that could be called chicken GHRH receptors.

Therefore, only SEQ ID NO:4, but not the full breadth of the claim meets the written description provision of 35 U.S.C. § 112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. § 112 is severable from its enablement provision (see page 1115).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 5-7 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Porter et al. (Endocrinology, 136(5):1850, 1995).

Porter et al. teach human GHRH that stimulated GH release in chick pituitary cells (*e.g.*, Fig. 3). Though Porter et al. is silent with respect to a chicken GHRH receptor, in order for the chick pituitary cells tested to respond to human GHRH, a GHRH receptor was necessarily present in the pituitary cells. Note that the receptor is not claimed as isolated or purified.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Claire M. Kaufman, whose telephone number is (571) 272-0873. Dr. Kaufman can generally be reached Monday, Tuesday and Thursday from 9:00AM to 3:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached at (571) 272-0829.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Official papers filed by fax should be directed to (571) 273-8300. NOTE: If applicant *does* submit a paper by fax, the original signed copy should be retained by the applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Claire M. Kaufman, Ph.D.

Patent Examiner, Art Unit 1646

May 10, 2005